

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Inventors: Harlan W. Waksal

Serial No.: (Continuation Of 09/374,028)

Filing Date: (herewith)

For: Treatment of Refractory Human  
Tumors with Epidermal Growth Factor  
Receptor Antagonists

Anticipated Art Unit: 1642

Anticipated Examiner: J. Nichols

ASSISTANT COMMISSIONER  
FOR PATENTS  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

S I R:

The above-identified application is a continuation of Application Serial No. 09/374,028, which is co-pending with the above-identified application by virtue of a Notice of Appeal and request for three-month extension of time for reply to the outstanding Office Action dated October 24, 2000, which are filed herewith. As is indicated in the Notice of Appeal, the Commissioner is authorized to charge the fee for the extension of time to Deposit Account No. 11-0600.

**AMENDMENTS**

Prior to examination of the above-identified application, please enter the

following amendments.

**In the Specification:**

On page 1, please replace the paragraph between the title and the heading "BACKGROUND OF THE INVENTION" with the following paragraph:

–The present application is a continuation of U.S. Patent Application Serial No. 09/374,028, filed on August 13, 1999, which is a continuation-in-part of U.S. Patent Application Serial No. 09/312,284 filed on May 14, 1999. Both Application Serial No. 09/312,284 and Application Serial No. 09/374,028 are incorporated herein by reference.--

**In the Claims:**

Please amend claims 1, 8, 10, 21, 22, and 32, as follows:

1. (Amended) A method of inhibiting the growth of a refractory tumor capable of stimulation by a ligand of epidermal growth factor receptor (EGFR) in a human patient which comprises treating the human patient with a therapeutically effective amount of an EGFR/HER1 antagonist.
8. (Amended) A method according to claim 1 wherein the tumors are tumors of the breast, heart, lung, small intestine, colon, spleen, kidney, bladder, head and neck, ovary, prostate, brain, pancreas, skin, bone, bone marrow, blood, thymus, uterus, testicles, cervix, or liver.

10. (Amended) A method of inhibiting the growth of a refractory tumor capable of stimulation by a ligand of epidermal growth factor receptor (EGFR) in a human patient which comprises treating the human patient with a therapeutically effective amount of an EGFR/HER1 antagonist and radiation.
21. (Amended) A method according to claim 10 wherein the tumors are tumors of the breast, heart, lung, small intestine, colon, spleen, kidney, bladder, head and neck, ovary, prostate, brain, pancreas, skin, bone, bone marrow, blood, thymus, uterus, testicles, cervix, or liver.
22. (Amended) A method of inhibiting the growth of a refractory tumor capable of stimulation by a ligand of epidermal growth factor receptor (EGFR) in a human patient which comprises treating the human patient with a therapeutically effective amount of an EGFR/HER1 antagonist and a chemotherapeutic agent.
32. (Amended) A method according to claim 22 wherein the tumors are tumors of the breast, heart, lung, small intestine, colon, spleen, kidney, bladder, head and neck, ovary, prostate, brain, pancreas, skin, bone, bone marrow, blood, thymus, uterus, testicles, cervix, or liver.

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Please add the following new claims:

34. A method of inhibiting the growth of a refractory tumor capable of stimulation by a ligand of epidermal growth factor receptor (EGFR) in a human patient which comprises treating the human patient with a therapeutically effective amount of an EGFR/HER1 antagonist, wherein said refractory tumor has been treated with radiation, chemotherapy, or combinations thereof.
35. A method of inhibiting the growth of a refractory tumor capable of stimulation by a ligand of epidermal growth factor receptor (EGFR) in a human patient which comprises treating the human patient with a therapeutically effective amount of an EGFR/HER1 antagonist, wherein said refractory tumor has been treated with therapy selected from the group consisting of radiation, chemotherapy, and combinations thereof, and further wherein said therapy failed to produce a complete or partial response in the tumor.

#### **REMARKS**

Claims 1, 8, 10, 21, 22, and 32 have been amended and new claims 34 and 35 have been added. The amendments are identical to those made in parent application 09/374,028 in an Amendment Under 37 C.F.R. §1.111 on August 3, 2000. The new

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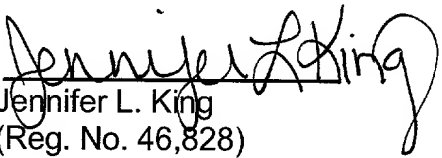
claims are added to cover additional aspects of the invention.

These amendments and additions to the claims and the amendment to the Specification are fully supported by the specification as originally filed. No new matter has been added.

Examination of this application is respectfully requested.

Respectfully submitted,

Date: 24 April 2001

  
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**Version With Markings To Show Changes Made**

**In the Specification:**

The replacement paragraph for the paragraph between the title and the heading "BACKGROUND OF THE INVENTION" on page 1 differs from the original paragraph as follows:

The present application is a continuation of U.S. Patent Application Serial No. 09/374,028, filed on August 13, 1999, which is a continuation-in-part of U.S. Patent Application Serial No. 09/312,284 filed on May 14, 1999[, which is] . Both Application Serial No. 09/312,284 and Application Serial No. 09/374,028 are incorporated herein by reference.

**In the Claims:**

The amended claims differ from the as-filed claims as follows:

1. (Amended) A method of inhibiting the growth of a refractory tumor[s] [that are stimulated] capable of stimulation by a ligand of epidermal growth factor receptor (EGFR) in a human patient[s,] which comprises [comprising] treating the human patient[s] with [an] a therapeutically effective amount of an EGFR/HER1 antagonist.
8. (Amended) A method according to claim 1 wherein the tumors are tumors of the breast, heart, lung, small intestine, colon, spleen, kidney, bladder, head and neck, ovary, prostate, brain, pancreas, skin, bone, bone marrow, blood, thymus, uterus, testicles, cervix, [and] or liver.

10. (Amended) A method of inhibiting the growth of a refractory tumor[s] [that are stimulated] capable of stimulation by a ligand of epidermal growth factor receptor (EGFR) in a human patient[s,] which comprises [comprising] treating the human patient[s] with [an] a therapeutically effective amount of an EGFR/HER1 antagonist and radiation.
21. (Amended) A method according to claim 10 wherein the tumors are tumors of the breast, heart, lung, small intestine, colon, spleen, kidney, bladder, head and neck, ovary, prostate, brain, pancreas, skin, bone, bone marrow, blood, thymus, uterus, testicles, cervix, [and] or liver.
22. (Amended) A method of inhibiting the growth of a refractory tumor[s] [that are stimulated] capable of stimulation by a ligand of epidermal growth factor receptor (EGFR) in a human patient[s,] which comprises [comprising] treating the human patient[s] with [an] a therapeutically effective amount of an EGFR/HER1 antagonist and a chemotherapeutic agent.
32. (Amended) A method according to claim 22 wherein the tumors are tumors of the breast, heart, lung, small intestine, colon, spleen, kidney, bladder, head and neck, ovary, prostate, brain, pancreas, skin, bone, bone marrow, blood, thymus, uterus, testicles, cervix, [and] or liver.